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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,923	12/19/2001	James Thacker	38599.0015	9929
25227	7590	05/05/2004		
MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			EXAMINER SHAHNAN SHAH, KHATOL S	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/020,923	<b>Applicant(s)</b> THACKER, JAMES	
	<b>Examiner</b> Khatol S Shahn-Shah	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-19 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,5-10,12 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3,5-19 and 22-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/01</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicant's amendment received 12/19/2001 is acknowledged. Specification page 1 was amended. Claims 2, 4, 20 and 21 were canceled. Abstract of disclosure was substituted with a new abstract.

### ***Election/Restrictions***

2. Applicant's election with traverse of February 23, 2004, is acknowledged. Applicant provisionally elected Group II claims 6-19 which are drawn to a method for identifying or detecting organisms using antibodies.

The traversal is on the ground that it would not be a serious burden on the examiner to examine multiple groups because they are all within class 435, has been noted. This is not found persuasive because while the searches may overlap but they are not coextensive. Because Groups I- III are drawn to different methods which differ in method objectives, steps, reagent and material used.

The requirement is still deemed proper and is therefore made **FINAL**.

In regard to the election of species in elected group II, applicant elected species of claim

11.

3. Currently claims 1, 3, 5-19 and 22-24 are pending.

4. Claims 1, 3, 5-10, 12-19, 22, 23 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

5. Currently claim 11 is under consideration.

### ***Information Disclosure Statement***

6. Applicants information disclosure of 12/19/2001 is acknowledged. The examiner has considered the references except JP 52078 95. No English translation of said document has been submitted. See attached form 1449.

### ***Drawings***

7. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No.

10053871. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the claims of both applications are drawn to a rapid method of detecting microorganisms in a sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rejected as being vague and indefinite for the recitation of "viability marker". The expression viability marker used in the claim is so unclear as to render the claim unclear with respect to the scope of the matter which protection is sought. In order to expedite the prosecution, examiner has considered the "viability marker" as a member of the formazan family.

Claim 11 is rejected as being vague and indefinite for the recitation of "reporter molecule". What are the metes and bounds of reporter molecules?

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 11 is rejected under 35 U.S. C. 103 (a) as being unpatentable over Shih et al. (US Patent 4,026,767, 1977) in view of Harlow and Lane (1986). Prior art of record, applicant's PTO form 1449.

Claim is directed to a method for detecting the presence of viable microorganisms by a Sandwich assay (direct assay, primary antibody-antigen- reporter molecule sandwich) comprising contacting said digested microorganisms with primary antibody to said viability marker.

Shih et al. teach a method of detecting the presence of microorganisms in blood or other fluids comprising contacting the material to be tested into a nutrient medium (see abstract) containing ditetrazolium chloride which converts to blue color component (blue color coloration due to formazan formation) in response to dehydrogenase reduction which takes place when microorganisms are present (see claim 1). Shih et al. further teach use of different tetrazolium salts in this method (column 2, lines 1-49). Thus Shih et al. teach a colorimetric assay by measuring formazan formation for detecting the presence of microorganisms. However Shih et al. do not teach using primary antibodies to viability marker (formazan). It would be obvious to a person of ordinary skill in the art to make the antibodies to formazan because Harlow and Lane teach raising monoclonal antibodies to antigen (such as formazan) and using them for direct and indirect immunoassays (see chapters 6 and 14).

It would be obvious to a person of ordinary skill in the art at the time the invention was made to modify the method taught by Shih et al by adding additional steps to amplify the signal generated after formazan formation because it would help to generate sensitive immunoassays

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with a reasonable expectation of success because Shih et al teach a method for detecting the presence of microorganisms in blood or other fluid comprising contacting the material to be tested into a nutrient medium containing ditetrazolium chloride which converts to detectable blue color component in response to dehydrogenase reduction which takes place when microorganism are present. Harlow and Lane taught the methodology for raising antibodies to antigen (such as formazan) and using them for immunoassays. An artisan of ordinary skills in the art would have been motivated to make such changes in methodology because it is well known in the art of immunoassays using specific antibodies are sensitive than colorimetric assays as taught by Shih et al.

### ***Conclusion***

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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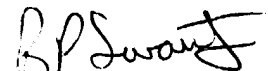
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnashah

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May 3, 2004

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER